

Message

From: Reaves, Elissa [Reaves.Elissa@epa.gov]
Sent: 12/9/2021 2:03:41 PM
To: Ozmen, Shamus [Ozmen.Shamus@epa.gov]; Lowit, Anna [Lowit.Anna@epa.gov]; Echeverria, Marietta [Echeverria.Marietta@epa.gov]
CC: Rosenblatt, Daniel [Rosenblatt.Dan@epa.gov]; Kiely, Timothy [Kiely.Timothy@epa.gov]; Cyran, Carissa [Cyran.Carissa@epa.gov]
Subject: RE: any changes by 9am please - RE: Follow-up - Press inquiry E&E News re: Glyphosate and cancer warning

No comments from me. Thanks Shamus

Elissa Reaves, Ph.D.
Director, Pesticide Re-evaluation Division
Office of Pesticide Programs
202-566-1925

From: Ozmen, Shamus <Ozmen.Shamus@epa.gov>
Sent: Thursday, December 9, 2021 9:02 AM
To: Lowit, Anna <Lowit.Anna@epa.gov>; Echeverria, Marietta <Echeverria.Marietta@epa.gov>; Reaves, Elissa <Reaves.Elissa@epa.gov>
Cc: Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>; Kiely, Timothy <Kiely.Timothy@epa.gov>; Cyran, Carissa <Cyran.Carissa@epa.gov>
Subject: RE: any changes by 9am please - RE: Follow-up - Press inquiry E&E News re: Glyphosate and cancer warning

Thank you Anna for the review.

Marietta and Elissa – I know folks are heading into the two-hour quarterly review meeting. We'll need keep this moving but if anything is a red flag, please let me know anyway so we can still address.

Draft Response

As discussed in EPA's *Revised Issue Paper: Evaluation of Carcinogenic Potential*, a collaborative research plan with the National Toxicology Program (NTP) of the National Institute of Environmental Health Sciences was developed to evaluate the role of glyphosate in product formulations and potential differences in formulation toxicity. To date, NTP has completed testing with glyphosate, glyphosate formulations, and a metabolite of glyphosate and has found no evidence of genotoxicity or induction of oxidative stress for any of the tested substances. This work has been presented at NTP Board of Scientific Counselors Meetings and other conferences. These presentations are available on the [NTP's website on glyphosate and glyphosate formulations](#). According to their website, NTP anticipates release of these data in 2022.

Additionally, the epidemiological studies considered in EPA's evaluation of the carcinogenic potential of glyphosate utilize exposure information based on use of pesticide products containing glyphosate, rather than the active ingredient glyphosate alone, to evaluate potential associations between glyphosate exposure and cancer outcomes. Overall, there was no evidence of an association between glyphosate exposure and numerous cancer outcomes. This includes the updated analyses of the Agricultural Health Study (AHS) cohort, which has followed a large number of pesticide applicators and their families since the 1990s, and did not report an association between glyphosate exposure and all cancer outcomes evaluated, including non-Hodgkin lymphoma (NHL). Furthermore, EPA has evaluated two journal articles that have been published since our completion of the Revised Issue Paper and determined that these studies did not impact EPA's cancer classification for glyphosate. As part of this evaluation, EPA has also updated the NHL meta-analyses to properly incorporate the updated analyses of the AHS cohort, which resulted in a lower non-statistically significant meta-risk ratio and further supports no association between glyphosate exposure and NHL. For additional

information, please refer to *Glyphosate: Response to Comments on the Proposed Interim Decision Regarding the Human Health Risk Assessment* and *Glyphosate: Epidemiology Review of Zhang et al (2019) and Leon et al. (2019) publications for Response to Comments on the Proposed Interim Decision.*

Thank you,

Shamus Ozmen
Communications Branch
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
Mobile: (571) 442-9844

From: Lowit, Anna <Lowit.Anna@epa.gov>
Sent: Thursday, December 9, 2021 8:43 AM
To: Ozmen, Shamus <Ozmen.Shamus@epa.gov>
Cc: Perron, Monique <Perron.Monique@epa.gov>; Nguyen, Khue <Nguyen.Khue@epa.gov>; Cyran, Carissa <Cyran.Carissa@epa.gov>; Vogel, Dana <Vogel.Dana@epa.gov>; Wilbur, Donald <Wilbur.Donald@epa.gov>; Akerman, Gregory <Akerman.Gregory@epa.gov>; Aubee, Catherine <Aubee.Catherine@epa.gov>; Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>; Echeverria, Marietta <Echeverria.Marietta@epa.gov>; Reaves, Elissa <Reaves.Elissa@epa.gov>; Kiely, Timothy <Kiely.Timothy@epa.gov>; Britton, Cathryn <Britton.Cathryn@epa.gov>; Muench, Andrew <muench.andrew@epa.gov>
Subject: Re: any changes by 9am please - RE: Follow-up - Press inquiry E&E News re: Glyphosate and cancer warning

This response looks good to me

Sent from my iPhone

On Dec 9, 2021, at 8:04 AM, Ozmen, Shamus <Ozmen.Shamus@epa.gov> wrote:

Thanks very much Monique. Yes, we'll continue to keep Anna on this email chain and in the loop going forward.

For RD and PRD folks, are there any concerns or changes on the draft below?

We are aiming to get this up to IO by 9:00 am if possible.

Thank you,

Shamus Ozmen
Communications Branch
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
Mobile: (571) 442-9844

From: Perron, Monique <Perron.Monique@epa.gov>
Sent: Wednesday, December 8, 2021 5:32 PM
To: Ozmen, Shamus <Ozmen.Shamus@epa.gov>; Nguyen, Khue <Nguyen.Khue@epa.gov>; Cyran, Carissa <Cyran.Carissa@epa.gov>; Vogel, Dana <Vogel.Dana@epa.gov>; Wilbur, Donald <Wilbur.Donald@epa.gov>; Akerman, Gregory <Akerman.Gregory@epa.gov>
Cc: Aubee, Catherine <Aubee.Catherine@epa.gov>; Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>;

Echeverria, Marietta <Echeverria.Marietta@epa.gov>; Reaves, Elissa <Reaves.Elissa@epa.gov>; Kiely, Timothy <Kiely.Timothy@epa.gov>; Britton, Cathryn <Britton.Cathryn@epa.gov>; Muench, Andrew <muench.andrew@epa.gov>; Lowit, Anna <Lowit.Anna@epa.gov>

Subject: RE: Follow-up - Press inquiry E&E News re: Glyphosate and cancer warning; DDL COB 12/8

Hi Shamus,

Here is the response we drafted for the reporter's follow-up question. This has only been reviewed by HED IO. All glyphosate responses should go through Anna Lowit as well so please make sure she is included in the OPP IO review.

Thanks,
Monique

Draft Response

Ex. 5 Deliberative Process (DP)

***DRAFT.INTERNAL.DELIBERATIVE.
DO NOT DISTRIBUTE.***

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Monique Perron  
U.S. Environmental Protection Agency  
Office of Pesticide Programs | Health Effects Division  
Senior Science Advisor  
*Email:* [perron.monique@epa.gov](mailto:perron.monique@epa.gov)  
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**From:** Ozmen, Shamus <[Ozmen.Shamus@epa.gov](mailto:Ozmen.Shamus@epa.gov)>

**Sent:** Wednesday, December 8, 2021 5:22 PM

**To:** Nguyen, Khue <[Nguyen.Khue@epa.gov](mailto:Nguyen.Khue@epa.gov)>; Cyran, Carissa <[Cyran.Carissa@epa.gov](mailto:Cyran.Carissa@epa.gov)>; Vogel, Dana <[Vogel.Dana@epa.gov](mailto:Vogel.Dana@epa.gov)>; Wilbur, Donald <[Wilbur.Donald@epa.gov](mailto:Wilbur.Donald@epa.gov)>; Akerman, Gregory <[Akerman.Gregory@epa.gov](mailto:Akerman.Gregory@epa.gov)>; Perron, Monique <[Perron.Monique@epa.gov](mailto:Perron.Monique@epa.gov)>

**Cc:** Aubee, Catherine <[Aubee.Catherine@epa.gov](mailto:Aubee.Catherine@epa.gov)>; Rosenblatt, Daniel <[Rosenblatt.Dan@epa.gov](mailto:Rosenblatt.Dan@epa.gov)>; Echeverria, Marietta <[Echeverria.Marietta@epa.gov](mailto:Echeverria.Marietta@epa.gov)>; Reaves, Elissa <[Reaves.Elissa@epa.gov](mailto:Reaves.Elissa@epa.gov)>; Kiely, Timothy <[Kiely.Timothy@epa.gov](mailto:Kiely.Timothy@epa.gov)>; Britton, Cathryn <[Britton.Cathryn@epa.gov](mailto:Britton.Cathryn@epa.gov)>; Muench, Andrew <[muench.andrew@epa.gov](mailto:muench.andrew@epa.gov)>

**Subject:** RE: Follow-up - Press inquiry E&E News re: Glyphosate and cancer warning; DDL COB 12/8

Many thanks Khue. The earliest possible in the morning would be greatly appreciated.

OPP IO and then Michal will need time to review and approve before the reporter files the story tomorrow at noon.

Apologies for such a tight turn-around on this follow-up question.

Thank you,

Shamus Ozmen  
Communications Branch  
Office of Chemical Safety and Pollution Prevention  
U.S. Environmental Protection Agency  
Mobile: (571) 442-9844

---

**From:** Nguyen, Khue <[Nguyen.Khue@epa.gov](mailto:Nguyen.Khue@epa.gov)>

**Sent:** Wednesday, December 8, 2021 5:04 PM

**To:** Ozmen, Shamus <[Ozmen.Shamus@epa.gov](mailto:Ozmen.Shamus@epa.gov)>; Cyran, Carissa <[Cyran.Carissa@epa.gov](mailto:Cyran.Carissa@epa.gov)>; Vogel, Dana <[Vogel.Dana@epa.gov](mailto:Vogel.Dana@epa.gov)>; Wilbur, Donald <[Wilbur.Donald@epa.gov](mailto:Wilbur.Donald@epa.gov)>; Akerman, Gregory <[Akerman.Gregory@epa.gov](mailto:Akerman.Gregory@epa.gov)>; Perron, Monique <[Perron.Monique@epa.gov](mailto:Perron.Monique@epa.gov)>

**Cc:** Aubee, Catherine <[Aubee.Catherine@epa.gov](mailto:Aubee.Catherine@epa.gov)>; Rosenblatt, Daniel <[Rosenblatt.Dan@epa.gov](mailto:Rosenblatt.Dan@epa.gov)>; Echeverria, Marietta <[Echeverria.Marietta@epa.gov](mailto:Echeverria.Marietta@epa.gov)>; Reaves, Elissa <[Reaves.Elissa@epa.gov](mailto:Reaves.Elissa@epa.gov)>; Kiely, Timothy <[Kiely.Timothy@epa.gov](mailto:Kiely.Timothy@epa.gov)>; Britton, Cathryn <[Britton.Cathryn@epa.gov](mailto:Britton.Cathryn@epa.gov)>; Muench, Andrew <[muench.andrew@epa.gov](mailto:muench.andrew@epa.gov)>

**Subject:** RE: Follow-up - Press inquiry E&E News re: Glyphosate and cancer warning; DDL COB 12/8

Hi Shamus,

HED is working on this right now, is there a deadline for a response?

Thanks,

Khue Nguyen  
Team Leader  
Risk Management and Implementation Branch 5  
Pesticide Reevaluation Division (PRD)

Office of Pesticide Programs, EPA  
202-566-2356  
[Nguyen.khue@epa.gov](mailto:Nguyen.khue@epa.gov)

---

**From:** Ozmen, Shamus <[Ozmen.Shamus@epa.gov](mailto:Ozmen.Shamus@epa.gov)>  
**Sent:** Wednesday, December 08, 2021 3:10 PM  
**To:** Cyran, Carissa <[Cyran.Carissa@epa.gov](mailto:Cyran.Carissa@epa.gov)>; Vogel, Dana <[Vogel.Dana@epa.gov](mailto:Vogel.Dana@epa.gov)>; Wilbur, Donald <[Wilbur.Donald@epa.gov](mailto:Wilbur.Donald@epa.gov)>; Akerman, Gregory <[Akerman.Gregory@epa.gov](mailto:Akerman.Gregory@epa.gov)>; Perron, Monique <[Perron.Monique@epa.gov](mailto:Perron.Monique@epa.gov)>  
**Cc:** Aubee, Catherine <[Aubee.Catherine@epa.gov](mailto:Aubee.Catherine@epa.gov)>; Rosenblatt, Daniel <[Rosenblatt.Dan@epa.gov](mailto:Rosenblatt.Dan@epa.gov)>; Echeverria, Marietta <[Echeverria.Marietta@epa.gov](mailto:Echeverria.Marietta@epa.gov)>; Reaves, Elissa <[Reaves.Elissa@epa.gov](mailto:Reaves.Elissa@epa.gov)>; Kiely, Timothy <[Kiely.Timothy@epa.gov](mailto:Kiely.Timothy@epa.gov)>; Britton, Cathryn <[Britton.Cathryn@epa.gov](mailto:Britton.Cathryn@epa.gov)>; Muench, Andrew <[muench.andrew@epa.gov](mailto:muench.andrew@epa.gov)>; Nguyen, Khue <[Nguyen.Khue@epa.gov](mailto:Nguyen.Khue@epa.gov)>  
**Subject:** Follow-up - Press inquiry E&E News re: Glyphosate and cancer warning; DDL COB 12/8

Hello,

Thank you very much for working on the E&E glyphosate inquiry (original at the bottom) and looping folks in. Carissa is out of the office this afternoon so I'm helping to move a follow-up question:

Follow-up:

I had one follow-up question. The attorneys for Edwin Hardeman also argue in the Monsanto case that EPA has acknowledged the need for more data on the risks of *formulations containing glyphosate* (rather than glyphosate itself), but it has yet to collect that information. Have there been any updates on that front that I should know about?

Is there a new collection of data regarding formulations or messaging we are comfortable with regarding the need/progress of these data?

Thanks,  
Shamus

For reference, here is the final response to the initial inquiry that OPA sent:

While EPA is not a party to this litigation, the following is information on EPA's review of glyphosate, including the agency's cancer determination.

On January 27, 2020, EPA released the glyphosate Interim Decision (ID) for registration review. As part of this action, EPA continues to find that there are no risks of concern to human health when glyphosate is used in accordance with current product labels. EPA also conducted an independent evaluation of the human carcinogenic potential of glyphosate as part of registration review and concluded that glyphosate is not likely to be a human carcinogen. EPA's comprehensive evaluation, which is described in EPA's Revised Issue Paper: Evaluation of Carcinogenic Potential, included an in-depth review of an extensive database of relevant studies submitted to the EPA or published in the open literature. EPA's cancer classification is in line with recent findings by many international expert panels and regulatory authorities, such as the Canadian Pest Management Regulatory Agency, Australian Pesticide and Veterinary Medicines Authority, European Food Safety Authority, German Federal Institute for Occupational Safety and Health, New Zealand Environmental Protection Authority, and the Food Safety Commission of Japan and the Joint Food and Agriculture Organization/World Health Organization Meeting on Pesticide Residues.

On November 12, 2021, EPA completed the next step in the [registration review process](#) and released the final [glyphosate Biological Evaluation](#) (BE) along with a summary of comments received on the draft BE and EPA's responses. In addition to evaluating toxicity and estimated exposure, the BE considered where glyphosate can be legally applied and compared this information to the ranges of U.S. threatened and endangered species. The BE also evaluated potential impacts of sublethal toxic effects and effects that are not due to direct toxicity (e.g., habitat modification). EPA has initiated consultation under the Endangered Species Act with the Services and is evaluating whether additional mitigation is needed to address ecological risks beyond what was required in the glyphosate ID.

The glyphosate registration review docket [EPA-HQ-OPP-2009-0361](#) at [www.regulations.gov](#) includes all supporting documents EPA used to make the registration review interim decision. Additionally, all documents related to the 2016 FIFRA Scientific Advisory Panel (SAP) on EPA's Evaluation of Glyphosate's Carcinogenic Potential can be found in docket [EPA-HQ-OPP-2016-0385](#) at [www.regulations.gov](#). Information on glyphosate can also be found EPA's website.

---

**From:** Vogel, Dana <[Vogel.Dana@epa.gov](mailto:Vogel.Dana@epa.gov)>

**Sent:** Tuesday, December 7, 2021 12:12 PM

**To:** Cyran, Carissa <[Cyran.Carissa@epa.gov](mailto:Cyran.Carissa@epa.gov)>; Wilbur, Donald <[Wilbur.Donald@epa.gov](mailto:Wilbur.Donald@epa.gov)>; Akerman, Gregory <[Akerman.Gregory@epa.gov](mailto:Akerman.Gregory@epa.gov)>; Perron, Monique <[Perron.Monique@epa.gov](mailto:Perron.Monique@epa.gov)>; Aubee, Catherine <[Aubee.Catherine@epa.gov](mailto:Aubee.Catherine@epa.gov)>; Rosenblatt, Daniel <[Rosenblatt.Dan@epa.gov](mailto:Rosenblatt.Dan@epa.gov)>; Echeverria, Marietta <[Echeverria.Marietta@epa.gov](mailto:Echeverria.Marietta@epa.gov)>

**Cc:** Reaves, Elissa <[Reaves.Elissa@epa.gov](mailto:Reaves.Elissa@epa.gov)>; Kiely, Timothy <[Kiely.Timothy@epa.gov](mailto:Kiely.Timothy@epa.gov)>; Britton, Cathryn <[Britton.Cathryn@epa.gov](mailto:Britton.Cathryn@epa.gov)>; Muench, Andrew <[muench.andrew@epa.gov](mailto:muench.andrew@epa.gov)>; Nguyen, Khue <[Nguyen.Khue@epa.gov](mailto:Nguyen.Khue@epa.gov)>

**Subject:** RE: FOR HED REVIEW: Press inquiry E&E News re: Glyphosate and cancer warning; DDL: 3:00 pm today

Adding RD to this email chain since they are part of the team working on the glyphosate prop 65 issue and this inquiry overlaps with that effort.

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**From:** Cyran, Carissa <[Cyran.Carissa@epa.gov](mailto:Cyran.Carissa@epa.gov)>

**Sent:** Tuesday, December 07, 2021 12:08 PM

**To:** Vogel, Dana <[Vogel.Dana@epa.gov](mailto:Vogel.Dana@epa.gov)>; Wilbur, Donald <[Wilbur.Donald@epa.gov](mailto:Wilbur.Donald@epa.gov)>; Akerman, Gregory <[Akerman.Gregory@epa.gov](mailto:Akerman.Gregory@epa.gov)>; Perron, Monique <[Perron.Monique@epa.gov](mailto:Perron.Monique@epa.gov)>

**Cc:** Reaves, Elissa <[Reaves.Elissa@epa.gov](mailto:Reaves.Elissa@epa.gov)>; Kiely, Timothy <[Kiely.Timothy@epa.gov](mailto:Kiely.Timothy@epa.gov)>; Britton, Cathryn <[Britton.Cathryn@epa.gov](mailto:Britton.Cathryn@epa.gov)>; Muench, Andrew <[muench.andrew@epa.gov](mailto:muench.andrew@epa.gov)>; Nguyen, Khue <[Nguyen.Khue@epa.gov](mailto:Nguyen.Khue@epa.gov)>

**Subject:** FOR HED REVIEW: Press inquiry E&E News re: Glyphosate and cancer warning; DDL: 3:00 pm today

**Importance:** High

Hello,

We received a press inquiry from E&E news concerning glyphosate and the latest lawsuit against Monsanto. The reporter's deadline is COB today. Linked below is a proposed response with language that has been used in past for glyphosate inquiries.

**Can you please review and provide any comments by 3:00 p.m. today?**

E&E News Response

Many thanks,  
Carissa

Carissa Cyran

Communications Branch  
Office of Chemical Safety and Pollution Prevention  
U.S. Environmental Protection Agency  
(202) 566 -1353

*(Pronouns: she/her/hers)*

---

**From:** Milbourn, Cathy <[Milbourn.Cathy@epa.gov](mailto:Milbourn.Cathy@epa.gov)>  
**Sent:** Tuesday, December 7, 2021 11:25 AM  
**To:** Dunton, Cheryl <[Dunton.Cheryl@epa.gov](mailto:Dunton.Cheryl@epa.gov)>; Scheifele, Hans <[Scheifele.Hans@epa.gov](mailto:Scheifele.Hans@epa.gov)>  
**Cc:** OPS CSID CB <[OPS\\_CSID\\_CB@epa.gov](mailto:OPS_CSID_CB@epa.gov)>  
**Subject:** E&E News--Deadline today -- Glyphosate

Hi Cheryl and Hans,

I'm sure we won't have much to say—please let me know.

Thanks,

Cathy

---

**From:** Pamela King <[pking@eenews.net](mailto:pking@eenews.net)>  
**Sent:** Tuesday, December 7, 2021 7:44 AM  
**To:** EPA Press Office <[Press@epa.gov](mailto:Press@epa.gov)>  
**Subject:** Deadline today -- Glyphosate

Good morning,

I'm working on a story about the Monsanto v. Hardeman Supreme Court petition related to the \$25 million jury verdict for Edwin Hardeman in the Roundup cancer case.

A lot of Monsanto's claims hinge on the EPA's authorization of the sale of Roundup, approval of Roundup sales without a cancer warning and finding that a cancer warning would "misbrand" the product.

Can someone help me understand EPA's latest moves on Roundup and glyphosate? I want to make sure I'm correctly characterizing the agency's current findings.

Thank you,

## **Pamela King**

Legal Editor, E&E News | **POLITICO**

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she/her

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